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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,970	10/29/2003	Mohan Gopalkrishna Kulkarni	11378.52US01	8985
23552	7590	03/16/2006	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			BERNSHTEYN, MICHAEL	
			ART UNIT	PAPER NUMBER
			1713	

DATE MAILED: 03/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/697,970	KULKARNI ET AL.	
	Examiner	Art Unit	
	Michael Bernshteyn	1713	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-17 is/are pending in the application.
- 4a) Of the above claim(s) 4-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. This Office Action follows a response filed on December 28, 2005. Applicants have amended claim 1 and canceled claim 2 without prejudice. Claims 4-17 are withdrawn from consideration.
2. Claims 1 and 3 are pending.

Claim Rejections - 35 USC § 103

3. The test of this section of Title 35, U.S.C. not included in this action can be found in a prior Office Action.
4. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loomis (U.S. Patent 6,403,758) in view of Mandeville et al. (U. S. Patent 5,891,862) for the rationale recited in paragraph 12 of Office Action dated on August 30, 2005.

Response to Arguments

5. Applicants did not elect specie for "each of the above genera" although it is absolutely clear that the species should be elected only for claim 1 which contains different species for R₁, R₂, and especially for Y because there are no species in claim 3. Only these two claims are pending.
1. Applicants did not make any changes concerning Information Disclosure Statement. Examiner has to repeat again that the listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the

Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered. Additionally, the information disclosure statement (IDS) was not submitted on 10/29/2003 and after the mailing date of the Application 10/697181 on 10/29/2003. The submission must be in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has to be considered by the examiner.

6. According to the amendments made by the Applicants, the rejection of claim 1 under 35 USC 112 is withdrawn.

7. Applicants traverse the rejection of claims under 35 U.S.C. 103 (a) as being unpatentable as obvious over Loomis (U.S. Patent 6,403,758) in view of Mandeville et al. (U. S. Patent 5,891,862). Applicant's arguments have been fully considered but they are not persuasive.

8. Applicants contend that Loomis provides only generic disclosure of some tri-block copolymers, with the formula xABAx (col. 4, lines 11-18). None of the x, A, or B of Loomis is even similar to the blocks of claimed copolymer. As a consequence, the specific tri-block as claimed are not and cannot be disclosed or suggested by Loomis. Therefore, a tri-block copolymer with the presently claimed structure is not obvious in view of Loomis.

Applicants contend that Loomis discloses the use of polysaccharides in the backbone of polymer chains, and the presently claimed invention does not use polysaccharides as a part of the backbone of the chain of the tri-block copolymer.

In response to applicant's arguments it is worth to mention that Loomis discloses crosslinked compositions formed from a water-insoluble copolymer. These compositions are copolymers having a **bioreasonable region**, a hydrophilic region and at least two crosslinkable functional groups per polymer chain (abstract). He discloses that said copolymer is selected from the group consisting of di-block copolymers, **tri-block copolymers**, and star copolymers (claim 6, col. 12, lines 41-44) and said tri-block copolymer has the general formula: $xABAx$ wherein A is the bioresorbable region, B is the hydrophilic region, and x is the crosslinkable functional group (claim 7, col. 12, lines 45-53). There is no specific limitation where exactly the bioreasonable region is located: in the main chain or as a part of the backbone.

9. Applicants contend that Mandeville fails to disclose the monomeric units, side chains, or linking groups employed in the claimed tri-block copolymer. Mandeville employs a sulfur atom in the side chain of monomer units in Formula VIII as a link to the fucoside moiety. The presently claimed tri-block copolymer does not include a sulfur atom on the side chain of the monomeric unit. The presently claimed tri-block copolymer includes a sulfur atom in the group that couples one block to another block, which group is at the end of the block. The moiety that forms a bond between the blocks, "X" as recited in claim 1, is an ester or amide link, and not a sulfur atom.

In response to applicant's arguments it is worth to mention that Mandeville discloses that a spacer group can be a straight chain or branched, substituted or unsubstituted alkylene group, wherein, optionally, one or more carbon atoms are substituted by heteroatoms, such as oxygen, nitrogen or **sulfur** atoms. Examples include a $-(CH_2)_n-$ group, wherein n is an integer from about 2 to about 12, a substituted alkylene group, such as $-(CH_2)_2 O[(CH_2)_2 O]_n$, $-(CH_2)_2 -$, wherein n is an integer, or a thiaalkylene group, such as $-(CH_2)_n S(CH_2)_m -$, where n and m are each an integer (col. 3 lines 10-18 and 41-43).

Mandeville discloses that the polymer characterized by polymerized monomer of Formula III containing polysaccharide residues (fucoside moiety) can be polymerized via a spacer group containing **s-heteroatom** (abstract), wherein this spacer group is substantially identical to the one instantly claimed (col. 3, lines 52-59 and col. 24, lines 3-12). Furthermore, by the virtue of copolymerization of two fucoside-bearing monomers with the same activity towards each other, as in Mandeville, the block copolymer is inherently formed (claim 12, col.24, lines 38-40).

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to obtain a tri-block copolymers from two bioresorbable regions and one hydrophilic region as taught by Loomis using the **S-R-S containing spacer groups** as taught by Mandeville in order to increase the hydrophilic (affinity for water) of the resulting material or substance and also for creation the compositions when placed in contact with an aqueous environment form hydrogels which are useful as sealant for porous materials and particularly for implantable prostheses. Furthermore, these

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hydrogels can be used as delivery vehicles for therapeutic agents as suggested by Loomis (col. 1, lines 20-28 and col. 5, lines 47-48). These two references essentially show that such polymers or copolymers comprising one or more fucoside (polysaccharide) moieties can inhibit or prevent rotavirus infection in a mammal (US'862, abstract) and thus to arrive at the subject matter of claim 1 of Application No. 10/697,970.

10. Applicants submit that the presently claimed invention does not make use of fucoside or fucoside moiety. Mandeville teaches monomers including a fucoside moiety (abstract and col. 2, lines 18-20). The presently claimed invention recites a block copolymer having the formula recited in claim 1. Fucoside is not recited in claim 1. Therefore, one skilled in the art would not learn how to create a block copolymer including two copolymers and an ester or amide link without a fucoside moiety present. The presently claimed invention is not participated by or obvious in view of Mandeville.

Accordingly, Applicants submit that the combination of Loomis and Mandeville fails to satisfy the requirements necessary to establish a *prima facie* case of obviousness.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, Mandeville discloses polymerizable monomers comprising a fucoside moiety. It is worth to mention that Mandeville discloses the usage of glucoside moieties, which can be, for example, fucoside moieties or sialic acid moieties (abstract). Sialic acid moiety is clearly shown like specie of Y in instant claim 1.

That means that fucoside moiety is functionally equivalent of sialic acid moiety and can substitute each other.

11. In the light of the discussion above, the rejection of record has not been withdrawn. The rejection remains in force.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

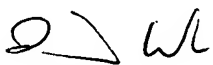
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Bernshteyn whose telephone number is 571-272-2411. The examiner can normally be reached on M-F 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on 571-272-1114. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Bernshteyn
Examiner
Art Unit 1713

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03/14/2006


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